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Treatment of Early Post-op Wound Infection after Internal Fixation

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14. ABSTRACT

Postoperative infection is one of the most prevalent and challenging complications faced by orthopaedic surgeons and patients in both the military and civilian populations. The wounds are contaminated or colonized at the time of injury, during the course of therapy, or both. Infection is always a possibility with any surgical intervention, particularly in the setting of orthopaedic trauma where multiple factors make the prevention and treatment of these infections very complicated.

As a result of slow enrollment at the five pilot sites, investigators consulted with several Infectious Disease specialists and discussed ways to expand the study population. The expansion will include all fractures or fusions involving long bone after internal fixation or joint fusion. The primary goal is to delineate optimal or equivalency or the antibiotic drug delivery method of IV vs PO. The study team felt that these changes needed to be made in order to move the study forward. As a result of the study population changes, we have changed the primary study outcome from a binary outcome (treatment failure) to a continuous outcome (number of surgeries) in order to maximize statistical power. During the protocol modification and review period, the five pilot sites continued to recruit and enroll patients and the data collection forms were modified and reviewed by the protocol committee. The changes are being finalized and the study materials distributed to the rest of the participating centers for training and implementation by the end of this calendar year.

15. SUBJECT TERMS
PO, IV, Antibiotics, plate, fixation, infection

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Introduction:
Severe fractures are common in modern warfare with fractures being fixed via internal fixation of plates and screws to hold the fracture stable while the bone heals. Approximately 10%-40% of severe fractures fixed with internal fixation develop a deep wound infection during the healing process. Thus, the overall goals of this study are to (1) evaluate the effect of treatment of post-op wound infection in long
bones after fracture fixation or joint fusion and either: (Group 1) operative debridement and PO antibiotic treatment for 6 weeks; or (Group 2) operative debridement and IV antibiotics for 6 weeks and (2) build and validate a risk prediction model for failure of treatment of early postoperative wound infections after fixation of fractures or joint fusion.

Body:
During the current reporting period, the Principal Investigator (PI) focused on administrative tasks essential to recruitment and enrollment into the study. As a result of slow enrollment at the five pilot sites, the study PI, MCC PI and the protocol committee met, in consultation with several Infectious Disease specialist consultants , and discussed ways to expand the study population. We decided to expand inclusion criteria to include all fractures or fusions involving long bone after internal fixation or joint fusion. The primary goal is to delineate optimal or equivalency or the antibiotic drug delivery method of IV vs PO. The study team felt that these changes needed to be made in order to move the study forward. Also as a result of the study population changes, we have changed the primary study outcome from a binary outcome (treatment failure) to a continuous outcome (number of surgeries) in order to maximize statistical power. We have submitted the modifications for master protocol approval at the MCC and received IRB approval. The DoD OHRP has designated these changes as minor and while they were submitted and reviewed, we did not require official approval from them.
During the protocol modification and review period, the five pilot sites continued to recruit and enroll patients. To date there have been 5 patients enrolled in the study. Also during this time, the data collection forms were modified and reviewed by the protocol committee. The changes are being finalized and the study materials are being distributed to the rest of the participating centers where we plan to train and obtain IRB approval, recruit and enroll patients before the end of this calendar year.

Task 1	Months 1-6	Completed
Task 2	Months 2-6	Completed
Task 3	Months 7-30	Roll out of enrollment – in progress
Task 4	Months 7-42	Enrollment ongoing
Task 5	Months 43-48	Not yet initiated

PROBLEM AREAS:
Enrollment – Inclusion criteria so "pure" that practicality of adequate enrollment was not feasible. Enrollment criteria have been expanded.

Glowcaps - During this past year we had some minor technical issues with the company supporting the GlowCaps. The company (formerly Vitality) has changed hands twice over the year and the contracts needed to be revised. During this time we re-negotiated the contracts and have finalized them after much back and forth. We now have some portion of the GlowCaps on hand for the PO group and anticipated having all product received prior to the roll out of the study to the rest of the sites.

NEXT STEPS:

- Disseminate protocol to the rest of the participating center
- Increase Enrollment
- Develop Reports related to project deliverables for Consortium

Key Research Accomplishments:
CRFs complete, Inclusion criteria expanded, 5 patients enrolled and followed

Reportable Outcomes:

None

Conclusion:
None

References:

None

Appendices:

None